Review of the Draft Baseline Human Health Risk Assessment (GSH, 2019)
Newark Bay Study Area
Comments prepared: 30 April 2019

No.	Topic	Section/ Page Ref.	Comments from TRW	GSH Response	EPA Backcheck Response (August 28, 2019)	GSH Response
1.	Lead Risk Characterization	Appendix E	*Question 1: The exposure assumptions are 13 days/year for a young child and 38 days/year for an adult. Considering the steady-state nature of the models is it appropriate to evaluate lead exposures under these conditions.* The exposure frequencies and durations for the scenarios are not clearly stated in Appendix E and the exposures do not use an appropriate averaging time (minimum is 1 day per week for 13 consecutive weeks). The 13 days for swimmers and boaters should us an averaging time of no more than 91 days. It is unlikely that some of these activities will occur in the winter months. This comment applies to all exposure scenarios. The exposure scenario for the wading child (exposure to site sediment) is not assessed correctly. It appears that some of the media exposures were zeroed out in the IEUBK model run documentation provided in appendix E. Recreational exposures should be assessed using US EPA 2003 (Intermittent Exposure Guidance) by time weighting the sediment exposure with a residential soil lead concentration. In the absence of a site-specific residential soil lead concentration, average state or county data may be used to inform a reasonable residential soil lead concentration for time weighting.	The exposure frequencies and durations are included in Table E-2 and exposure frequencies are repeated in Table E-3. The averaging times have been revised to match the assumed duration of exposure (either 91 or 105 days) (pg. E-3). Even though the child wader (and swimmer) was assumed to be exposed to sediment 1 day per week for 3 months for other COPCs evaluated in the NBSA BHHRA, the IEUBK assumes exposure occurs for 365 days per year and this assumption cannot be changed in the model. Accordingly, the estimated blood lead concentrations for the child wader (and swimmer) were based on exposure 365 days per year, overstating the contribution of lead in sediment to child blood lead levels (pg. E-3). It is acknowledged that EPA's Intermittent Exposure Guidance could be used to estimate a time-weighted average concentration based on the measured sediment concentrations and an estimate of lead in residential soil. However, that was not deemed necessary because the mean lead concentration in sediment is 205.7 mg/kg, which is only slightly higher than the 200 mg/kg screening level recommended in EPA's comments. Any time-weighted concentration based on average state or county data would be below 200 mg/kg.	The averaging time was adjusted in accordance with the comment. Text explaining averaging time was added to page E3 and to Table E-3. The use of the 365 days for averaging time should be addressed in the text (Section E-3.1) and on Table E-3. In addition, the uncertainties with using 365 days versus 1 day per week for 3 months needs to be included as an uncertainty in Section E-6.	Comment noted. The text was revised in Section E-3.1 to address the use of the 365 days for average time. The 365 value is included in Table E-2, which is the child-specific table. Text was added to Section E-6 to address the uncertainty with using 365 days implemented in IEUBK vs. 1 day per week for 3 months.
2.	Lead Risk Characterization	Appendix E	*Question 2: The assessment relies on the Bowers 1994 model for the assessment of sediment exposure. It is unclear why Bowers was used in place of ALM. Is this appropriate? What are the potential impacts on the calculation of blood lead levels for these receptors?* While the preferred lead risk assessment tool for non-residential exposure scenarios is the Adult Lead Methodology, the Bowers model does accommodate non-soil exposures. Citing the comparison of adult risk models with strengths and weaknesses that was prepared by the TRW Lead Committee: US EPA 2001 (Review of Adult Lead Models) may be useful in this instance.	The text has been revised to note that the ALM model could not be used on its own because it does not account for exposure to lead via pathways other than soil (e.g., food) (pg. E-2. Further, as noted in USEPA 2001, "The Bowers *et al*. (1994) model was not included in this review effort, because of the similarity between the Bowers and ALM models. The basic algorithms for the Bowers model were used for the California Gulch site and form the basis for the current ALM	Text noting the ALM could not be used on its own was added as stated. Suggest adding the following sentence at the end of the last paragraph in Section E-1 (p. E-2): While the preferred lead risk assessment tool for non-residential exposure scenarios is the Adult Lead Methodology, the Bowers model does accommodate non-soil exposures. And	Comment noted. The suggested sentence was added to the end of the last paragraph in Section E-1 (p. E-2).

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				model." USEPA 2001 is already cited in Section E-4, but has been added to the end of Section E-1, where the models are first mentioned (pg. E-2).	in fact, the Bowers et al. (1994) model was not included in US EPA review (2001) of adult lead models because of the similarity between the Bowers and ALM models, i.e., the basic algorithms for the Bowers model form the basis for the ALM model (USEPA, 2001).	
3.	Lead Risk Characterization	Appendix E	*Question 3. Lead exposure in fish and crab tissues were evaluated. Is this appropriate and were the models selected appropriate?* If child recreators are expected to also consume crab meat from the site, their crab intake may be incorporated in the IEUBK model run that assesses the time-weighted sediment exposure by including crab intake as an alternate intake. This approach (additional intake) is suggested in the text of Section E-3.3, but it is not what is shown in the IEUBK model run documentation.	Section E-3.3 (Diet) states the following: "For the purpose of simplicity and to obtain a more conservative estimate of risk from diet, it was assumed that the consumption of crab was in excess of the default consumption of food. In other words, the dietary lead intake used in this assessment was the sum of the default lead intake plus the intake due to crab." A table has been added to the text showing the specific values, consistent with pages 1 and 2 of the IEUBK model output (pg. E-3 and pg. E-4).	A table has been placed in Section E-3.3 that shows age-specific IEUBK default ingestion rate which was increased by adding ingestion rate of crab. Please include in this text the math showing derivation of the crab rate of 2.863 ug/day. Also include where the fractional uptake of 0.50 (as described in the text) is accounted for in the total intake.	Comment noted. The text was revised in Section E-3.3 to show the calculation of 2.863 ug/day for crab excessive dietary intake rate. Excessive crab concentration was calculated as: $(EPC_{Pb_{crab\ hepatopancreas}} \cdot IR_{crab\ hepatopancreas} \cdot EF_{crab\ hepatopancreas}) / AT_{crab\ hepatopancreas} = \frac{0.411 \cdot 6.9\overline{6} \cdot 365}{365} = 2.863\ ug/day$ Here: $EPC_{Pb_{crab\ hepatopancreas}}$ is Exposure Point Concentration in mg/kg, $IR_{crab\ hepatopancreas}$ is Ingestion Rate in g/day, $EF_{crab\ hepatopancreas}$ is Exposure Frequency in days/year, and $AT_{crab\ hepatopancreas}$ is Averaging Time in days/year. The text has been revised to indicate that the fractional uptake (absorption) of 0.5 (or 50%) represents the default

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						value in "GI Values/Bioavailability" option of the IEUBK software. Please see Section E-3.3 (p. E-3).
4.	Lead Risk Characterization	Appendix E	In addition, the following comments were made: • It wasn't clear in the documentation which version of the IEUBK model was used (the current version can be found here: https://www.epa.gov/superfund/lead-superfund-sites-software-and-users-manuals). Also, the IEUBK model was not run using ages 12-72 months as indicated in the text. • In the Results Section (E-5) the results of the IEUBK model and ALM analyses are not expressed correctly. These risk tools provide results in terms of risk probability of exceeding a target blood lead concentration (FMI see US EPA 1994 and US EPA 1998). .	The model version was specified in the text as "IEUBK v1.11" and in the model output sheets as "Model Version: 1.1 Build 11." This is the current version of model found at the link provided. The text has been revised such that the model is consistently identified as IEUBK v1.1, Build 11 (pg. E-2 and pg. E-3). The results from the IEUBK model are in the form of predicted blood lead levels (see Attachment E-A) and as a probability plot (included in the text). For the adolescent and adult, the probability of exceeding the target blood level is provided in Table E-3. The text has been revised to include this information (pg. E-7). The form of these results is the same as that provided in the BHHRA for the Lower Passaic River Study Area (LPRSA).	The model version was called out in the draft and it is called out as v1.1, Build 11 in the revised appendix. Note that the IEUBK output shows that 12-72 months evaluated…however, the age range on the probability plots is shown as 12 to 84 months (see page 7 of 9 in Appendix E). Please revise the age ranges on the probability plots as necessary. Consistent with OLEM Directive 9200.2-167, the results should be stated in the form: "…has an estimated risk of no more than 5% of exceeding a 5 µg/dL blood lead level." Therefore, replace ">99% of child anglers/sportsmen, swimmers, and waders potentially exposed to lead under the conditions summarized above are predicted to exhibit PbBs lower than 5 µg/dL." With "<1% of child anglers/sportsmen, swimmers, and waders potentially exposed to lead under the conditions summarized above are predicted to exhibit PbBs higher than 5 µg/dL."	Calculations with revised age range (12-72 months) were performed and correct probability density plots are shown in Section E-5.1 (p. E-7). The text was revised, and suggested phrase was implemented. Please see Section E-5.1 (p. E-7).